

IN THE CLAIMS:

Please amend Claim 31 as the follows:

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31. (Amended) An antibody directed against an isolated IL-16 antagonist peptide consisting of
GMWQCLLS (SEQ ID NO:13).

REMARKS

In the Office Action dated August 23, 2002, the Examiner has set forth a requirement for restriction under 35 U.S.C. §121, alleging that the subject matter defined by the claims of the present invention represents the following four separate and distinct inventions:

- I. Claims 21, 29, 30, 32, 33, and 35, drawn to antibodies against sequences comprising CLLS, classified in class 530, subclass 388.1 and 389.1.
- II. Claims 21, 30, and 35, drawn to antibodies against sequences comprising WQALLS, classified in class 530, subclass 388.1 and 389.1.
- III. Claims 21, 30, and 34, drawn to antibodies against sequences comprising QVVA, classified in class 530, subclass 388.1 and 389.1.
- IV. Claims 21, 31, and 35, drawn to antibodies against sequences comprising GMWQLLS, classified in class 530, subclass 388.1 and 389.1.

Claim 31 has been amended to correct a typographical error. The sequence of claim 31, as amended, is supported by SEQ ID NO: 13 and the specification, for example, at page 10, lines 12-16. No new matter has been added. It is submitted that Group IV claims 21, 31 and 35 should be read to properly recite the sequence GMWQCLLS. Accordingly, Claim 31, as amended, belongs to both Group I and Group IV.

In order to be fully responsive to the Examiner's requirement for restriction, Applicants provisionally elect to prosecute the subject matter of Group I, Claims 21, 29, 30, 32, 33, 35 and amended Claim 31, directed antibodies against sequences comprising CLLS, for continued examination herein. Applicants reserve the right to file one or more divisional applications directed to the non-elected subject matter in this application.

However, pursuant to 37 C.F.R. §§1.111 and 1.143, Applicants hereby traverse the Examiner's requirement for restriction and request reconsideration thereof in view of the following remarks.

It is submitted that the Restriction Requirement is not in compliance with the requirements of the MPEP. It is noted that Groups I-IV are classified in the same class and subclasses. Applicants respectfully direct the Examiner's attention to MPEP § 808.02, which states "where however, the classification is the same and the field of search is the same and there is no clear indication of separate future classifications and field of search, no reasons exist for dividing among related inventions". As shown hereinabove, the classifications and the field of search of the various alleged groups are the same. The U.S. Patent and Trademark Office has not provided any evidence of separate feature classifications for this field of search. Thus, in accordance with the provisions of the MPEP, there is no reason for dividing among these clearly related inventions.

Moreover, an Examiner's authority to require restriction is defined and limited by statute:

If two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions.

35 U.S.C. § 121, first sentence (emphasis added). The implementing regulations of the Patent and Trademark Office include the mandate that restriction is appropriate only in cases presenting inventions which are both independent and distinct, 37 C.F.R. §§1.141-142. Without a showing of independence and distinctness, a restriction requirement is unauthorized. In the present application, the claims which the Examiner has grouped separately are not "independent and distinct" so as to justify the restriction requirement.

The Examiner alleges that the antibodies of Groups I-IV are different, each from the other, because they are generated against different peptides and thus are different molecules with different structure and functional characteristics.

Applicants respectfully submit that the claimed subject matter is directed to an independent and distinct invention as defined in 35 U.S.C. § 121. The claimed invention is related to IL-16 antagonists. In particular it relates to the discovery and isolation of novel peptides whose sequences coincide with regions of the IL-16 receptor (CD4), and antibodies raised against these peptides. The subject matter of Groups I-IV is drawn to antibodies against those IL-16 antagonist peptides whose sequences coincide with the corresponding sequences of a mammalian IL-16 protein. Thus, Groups I and II are interrelated and interdependent.

Moreover, the subject matter in Groups I-IV are functionally related, i.e. against those IL-16 antagonist peptides. Notably, Groups I and IV include peptides including the same epitope, i.e. "CLLS".

Therefore, Applicants respectfully submit that the subject matter in Groups I-IV are linked by a single inventive concept – they are merely different aspects of a single invention. Groups I-IV are not "independent and distinct".

Applicants respectfully submit that the courts have recognized that it is in the public interest to permit applicants to claim several aspects of their invention together in one application, as the applicants have done herein. The CCPA has observed:

We believe the constitutional purpose of the patent system is promoted by encouraging applicants to claim, and therefore to describe in the manner required by 35 U.S.C. §112 all aspects as to what they regard as their invention, regardless of the number of statutory classes involved.

In re Kuehl, 456 F.2d 658, 666, 117 U.S.P.Q. 250, 256 (CCPA 1973). This interest is consistent with the practical reality that a sufficiently detailed disclosure supporting claims to one aspect of an invention customarily is sufficient to support claims in the same application to other aspects of the same invention.

Applicants respectfully suggest that in view of the continued increase of official fees and the potential limitation of an applicant's financial resources, a practice which arbitrarily imposes restriction requirements may become prohibitive and thereby contravene the constitutional purpose to promote and encourage the progress of science and the useful arts. Moreover, under the regulatory changes as a consequence of the General Agreement on Trade and Tariffs (GATT), applicants are required, to conduct simultaneous prosecution, as here, requiring excessive filing costs, or to otherwise compromise the term of related patent assets.

It is vital to all applicants that restriction requirements issue only with the proper statutory authorization, because patents issuing on divisional applications which are filed to prosecute claims that the Examiner held to be independent and distinct can be vulnerable to legal challenges alleging double patenting. The third sentence of 35 U.S.C. §121, which states that a patent issuing on a parent application "shall not be used as a reference" against a divisional application or a patent issued thereon, does not provide comfort to applicants against such

allegations. The Court of Appeals for the Federal Circuit has declined to hold that § 121 protects a patentee from an allegation of same-invention double patenting, Studiengesellschaft Kohle GmbH v. Northern Petrochemical Co., 784 F.2d 351, 355, 288 U.S.P.Q. 837, 840 (Fed. Cir. 1986). In Gerber Garment Technology Inc. v. Lectra Systems Inc., 916 F.2d 683, 16 U.S.P.Q. 2d 1436 (Fed. Cir. 1990), the court held that §121 does not insulate a patentee from an allegation of "obviousness-type" double patenting, and in fact affirmed the invalidation on double patenting grounds of a patent that had issued from a divisional application filed following a restriction requirement. Furthermore, it is far from clear that the step of filing a terminal disclaimer is available to resolve a double patenting issue that arises after the issuance of a patent on the divisional application.

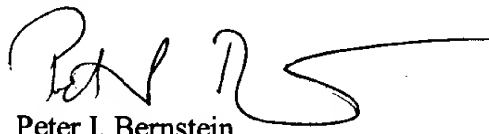
All these considerations indicate that the imposition of a restriction requirement with inadequate authority can lead to situations in which an applicant's legitimate patent rights are exposed to uncertainty and even extinguished. Accordingly, to protect a patentee's rights and to serve the public interest in the legitimacy of issued patents, Applicants respectfully urge the Examiner not to require restriction in cases such as the present application wherein various aspects in a unitary invention are claimed.

Finally, Applicants respectfully submit that a determination to make the pending restriction requirement final must evidence the patentable distinctness of all defined groups, one from the other, as presented by the Examiner.

Attached hereto is a marked-up version of the changes made to the claims by the instant amendment, captioned "**Versi n with Markings to Show Changes Made.**"

In view of the foregoing comments, it is respectfully urged that the Examiner reconsider and withdraw the requirement for restriction and provide an action on the merits with respect to all the claims.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Peter I. Bernstein", with a long horizontal flourish extending to the right.

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS:

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